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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/772,704	02/05/2004	George C. Tsokos	Army 178	5604
30951	7590	01/11/2007		
NASH & TITUS, LLC 21402 UNISON RD MIDDLEBURG, VA 20117			EXAMINER CHONG, KIMBERLY	
			ART UNIT	PAPER NUMBER
			1635	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/772,704

Applicant(s)

TSOKOS ET AL.

Examiner

Kimberly Chong

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 10, 11, 15, 29 and 30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 10, 11, 15, 29 and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/25/2006 has been entered.

Status of Application/Amendment/Claims

Applicant's response filed 10/25/2006 has been considered. Rejections and/or objections not reiterated from the previous office action mailed 08/25/2006 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 29 and 30 are rejected under 35 U.S.C. 102(a) as being anticipated by Tenbrock et al. (Journal of Immunology 2002 cited in PTO form 892 filed 01/17/2006).

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The instant claims are also drawn to a method of increasing IL-2 production in lymphocytes, such as T cells from a SLE patient comprising removing lymphocytes or T cells from a patient, leukophoresing lymphocytes and treating said lymphocytes or T cells with a antisense CREM to increase IL-2 production.

Tenbrock et al. teach a method of increasing IL-2 production in T cells from a SLE patient comprising obtaining blood from said SLE patients, separating the T cells from the blood cells and transfecting T cells with a plasmid construct comprising an antisense to CREM (see page 4148). It must be noted that "leukophoresed lymphocytes" are not defined in the specification and because cells belong to a group of white blood cells called lymphocytes, leukophoresed lymphocytes for purpose of prior art are considered T cells. Tenbrock et al. teach said antisense to CREM down-regulates CREM protein expression and up-regulates IL-2 mRNA in SLE T cells (see Figures 4, page 4150). Tenbrock et al. teach a decrease in IL-2 production on SLE patients is responsible for opportunistic infections in patients that could lead to death.

Thus, Tenbrock et al. anticipates the claims of the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 10-11 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tenbrock et al. (Journal of Immunology 2002 cited in PTO form 892 filed 01/17/2006) in view of Rosenberg, S. (US Patent No. 5,126,132).

The instant claims are drawn to a method of increasing IL-2 production in systemic lupus erythematosus (SLE) T cells in a patient that has SLE comprising administering gene modified T cells to said patient, said T cells having been modified with an antisense cAMP response element modulator (CREM) or a plasmid vector expressing an antisense CREM, thereby increasing the expression of IL-2 in said T cells in said patient. The instant claims are also drawn to a method of increasing IL-2 production in T cells from a SLE patient comprising removing T cells from a patient and treating said T cells with a antisense CREM to increase IL-2 production.

Tenbrock et al. teach a method of increasing IL-2 production in T cells from a SLE patient comprising obtaining blood from said SLE patients, separating the T cells from the blood cells and transfecting T cells with a plasmid construct comprising an antisense to CREM (see page 4148). It must be noted that "leukophoresed lymphocytes" are not defined in the specification and because T cells belong to a group of white blood cells called lymphocytes, leukophoresed lymphocytes for purpose of prior art considered T cells. Tenbrock et al. teach said antisense to CREM down-regulates CREM protein expression and up-regulates IL-2 mRNA in SLE T cells (see Figures 4, page 4150). Tenbrock et al. teach a decrease in IL-2 production on SLE patients is responsible for opportunistic infections in patients that could lead to death. Tenbrock et al. does not teach a method of administering T cells to a patient.

Rosenberg teach an immunotherapeutic method of introducing T cells that have been removed from a patient back to said patient for the treatment of diseases.

Rosenberg teach T cells removed from patients are cultured in vitro, collected by centrifugation and then re-infused intravenously back into the patient (see columns 3 and 4).

It would have been obvious to one of skill in the art to administer the gene modified T cells taught by Tenbrock et al., back into a patient for the treatment of disease, as taught by Rosenberg.

One of skill in the art would have been motivated to administer gene modified T cells by the methodology taught by Rosenberg to increase IL-2 production for the treatment of SLE in patients because Tenbrock et al. teach IL-2 production in T cells is important for the regulation of immune response and given that direct infusion of IL-2 have been limited by unwanted side effects (see page 4151). One would have been further motivated to deliver T cells with increased IL-2 production to SLE patients using the methodologies of Rosenberg because Rosenberg teach an efficient method of treating diseases in patients after infusion of T cells and due to the deleterious effects of decreased IL-2 production in SLE patients, as taught by Tenbrock et al., one would have been motivated to deliver modified T cells with the ability to increase IL-2 production in SLE patients.

Finally, one of skill in the art would have had a reasonable expectation of success given that Rosenberg teach an efficient method of isolating T cells and re-infusion of T cells back to the patient, a method that is routine to one of skill in the art.

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Further, one of skill in the art would have had a reasonable expectation of success that the delivered gene modified T cells would up-regulate IL-2 production given that Tenbrock et al. teach up-regulation of IL-2 in T cells of SLE patients after administration of an antisense to CREM.

Thus in the absence of evidence to the contrary, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

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Conclusion

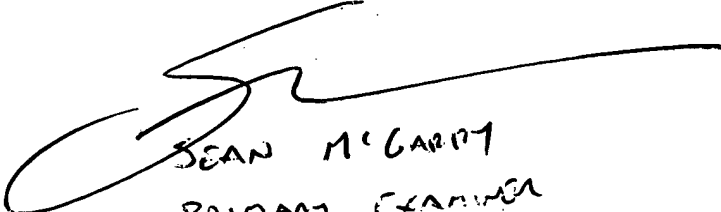
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Chong whose telephone number is 571-272-3111. The examiner can normally be reached Monday thru Friday between 7-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached at 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Kimberly Chong
Examiner
Art Unit 1635



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